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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,551	12/08/2003	Todd K. Whitehurst	AB-308U	4571

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ADVANCED BIONICS CORPORATION
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EXAMINER

GREENE, DANA D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,551

Applicant(s)

WHITEHURST ET AL.

Examiner

Dana D. Greene

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8-11-04 & 9-22-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Independent claims 1 and 9 and dependent claims stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bourgeois (US 5,058,584, hereinafter "Bourgeois") in view of Schulman et al. (US 5,358,514, hereinafter "Schulman"). Bourgeois is considered to disclose:

a method for treating a patient with angina pectoris comprising (see col. 1, ln. 2, col. 36-42, Bourgeois). The disclosed system and method is considered to anticipate the claimed method of treatment because both provide treatments for angina pectoris and/or for relieving its symptoms using one or more implantable stimulators for delivering electrical stimulation;

providing an implantable stimulator with at least one electrode and with a size and shape suitable for placement of the entire stimulator adjacent to a nerve (see col. 2, ln. 30-40, Bourgeois). The disclosed provision is considered to disclose the claimed method of providing an implantable stimulator because both methods teach the use of an implantable stimulator that is capable of being placed close enough to the structures to be stimulated;

implanting the stimulator adjacent to at least one tissue influencing the angina pectoris of the patient, which tissue is at least one of an intercostal nerve and an intercostal nerve branch (see col. 2, ln. 65 – col. 4, ln. 2, Bourgeois). The disclosed method of implanting is considered to anticipate the claimed method of implanting the stimulator because both methods advocate the implantation of a stimulator near an intercostals nerve for the purpose of treating angina pectoris and blocking the angina pain signals to the brain;

providing operating power to the stimulator; using an external appliance to transmit stimulation parameters to the stimulator; receiving the stimulation parameters at the stimulator; and generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator (see col. 2, ln. 40-58, Bourgeois). The disclosed method of providing operating parameters is considered to anticipate the claimed method of providing operating power because both methods teach the means of receiving power and /or data by inductive or radio-frequency (RF) coupling;

delivering stimulation pulses via the stimulator to the at least one of the intercostal nerves and intercostal nerve branches influencing angina pectoris as a treatment for angina pectoris (see col. 1, ln. 50-55, Bourgeois). The disclosed method of providing stimulation bursts is considered to anticipate the claimed method of delivering stimulation pulses because both methods are dedicated to sensory processes and advocate the delivery of stimulation to accessible peripheral and/or visceral nerves.

Bourgeois is considered to disclose the claimed invention as discussed above, except for the miniature leadless and miniature implantable stimulator. However, Schulman is considered to disclose the claimed miniature implantable stimulator (see col. 12, ln. 39-50, Schulman). It would have been obvious to one of ordinary skill in the art to combine the teachings of Bourgeois with the considered miniature implantable stimulator teaching found in Schulman for the purpose of providing treatments for angina pectoris by delivering electrical stimulation via a device such as the miniature implantable stimulator that can be implanted via a minimally invasive surgical procedure such as minimal punctures or incisions in the patient.

Dependent claims 2-7 and 10-17 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bourgeois in view of Schulman. As discussed above, under the obviousness rejection, Schulman is considered to disclose the claimed miniature implantable stimulator.

Claim 10 is taught by the combination of the Bourgeois and Schulman references. Bourgeois teaches the application of stimulation energy to electrodes by an insulated lead (see abstract, Bourgeois). It would have been obvious to one of ordinary

skill in the art to combine the teachings of Bourgeois with those of Schulman for the purpose of treating angina pectoris using electrical stimulation.

With reference to claims 2 and 11, Bourgeois is considered to teach the method of delivering excitatory stimulation pulses to the intercostal nerves and nerve branches (see abstract, Bourgeois). Bourgeois' application of high frequency stimulation energy is considered to teach the claimed method of delivering stimulation pulses because both acts provide continuous or intermittent stimulation for the provision of an adequate amount of treatment.

Referring to claims 3 and 12, Bourgeois is considered to teach the deliverance of stimulation pulses of less than about 15 mA (see col. 2, ln. 40-45, Bourgeois). The disclosed various operating parameters of the implantable pulse generator is considered to teach the claimed method of delivering stimulation pulses of low amplitudes because Bourgeois allows medical personal to adjust the amplitude of the pulse.


Finally, with reference to claims 4-7 and 13-17, Bourgeois is considered to teach a method of sensing conditions of a patient (see col. 2, ln. 30-40, Bourgeois). The disclosed utilization of an activity sensor is considered to teach the claimed method of sensing conditions of a patient because both are capable of determining relative activity levels of the patient. It would have been obvious to one of ordinary skill in the art to combine the teachings of Bourgeois with those of Schulman for the purpose of sensing the condition of a patient in connection with the use of a miniature stimulator.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-0276.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Dana D. Greene


George Manuel

Primary Examiner